

**TRANSMITTAL LETTER
(General - Patent Pending)**

Docket No.
112703-211

In Re Application Of: **Barabolak et al.**

Serial No.
10/035,320

Filing Date
November 8, 2001

Examiner
S. Rose

Group Art Unit
2531

Title: **ANTI-PLAQUE EMULSIONS AND PRODUCTS CONTAINING SAME**

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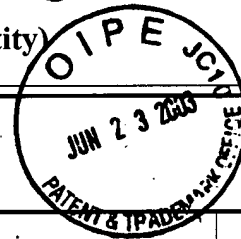
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R bert J. Buccieri

Typed or Printed Name of Person Mailing Correspondence

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TRANSMITTAL OF APPEAL BRIEF (Large Entity)Docket No.
112703-211In Re Application Of: **Barabolak et al.**Serial No.
10/035,320Filing Date
November 8, 2001Examiner
S. RoseGroup Art Unit
2531Invention: **ANTI-PLAQUE EMULSIONS AND PRODUCTS CONTAINING SAME****REC'D**

JUN 8 10 2003

TECH CENTER 1600/2300**TO THE COMMISSIONER FOR PATENTS:**

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on April 17, 2003

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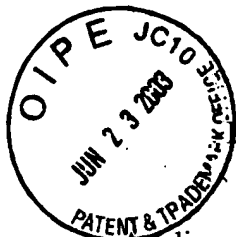
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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#14
1 of 3
JRP
7/2/03

Applicants: Barabolak et al.
Appl. No.: 10/035,320
Conf. No.: 2531
Filed: November 8, 2001
Title: ANTI-PLAQUE EMULSIONS AND PRODUCTS CONTAINING SAME
Art Unit: 2531
Examiner: S. Rose
Docket No.: 112703-211

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Dear Sir:

This Appeal Brief is submitted in support of the Notice of Appeal submitted by Appellants on April 17, 2003 in the above-identified patent application.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Wm. Wrigley Jr. Company by virtue of an Assignment dated October 27, 1999 and November 2, 1999 and recorded at the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellants do not believe there are any known appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

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III. STATUS OF THE CLAIMS

Claims 1-24 are pending in this application. A copy of appealed Claims 1-24 is attached in the appendix. In the Final Office dated January 10, 2003, Claims 1, 2, 4, 5, 15, 19 and 23 stand rejected under 35 U.S.C. § 102 as anticipated by U.S. Patent No. 5,236,699 ("*Libin I*"); Claims 3, 4, 20, 21 and 24 are rejected as obvious under 35 U.S.C. § 103 over *Libin I*; Claims 1, 2, 5-7, 9, 13-16 and 19 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,380,530 ("*Hill*") in view of *Libin I*; and Claims 1-7, 9-11, 13, 15-17 and 19-21 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,487,902 ("*Andersen*"). A copy of the Final Office Action is appended hereto as Exhibit A of the Supplemental Appendix and a copy of each of the cited references is appended hereto as Exhibits B-D of the Supplemental Appendix.

Appellants note for the record that Claims 1-22 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 and 10 of U.S. Patent No. 6,355,265 in view of *Libin I*; over Claims 10, 12 and 29 of U.S. Patent No. 6,322,806 in view of *Libin I*; over Claims 1, 9, 12, 17 and 26 of U.S. Patent No. 6,290,985 in view of *Libin I*; and claims of U.S. Patent Nos. 6,436,369 and 6,350,480. In response to the Final Office Action, Appellants submitted a terminal disclaimer to overcome the double patenting rejections. On May 16, 2003, the Patent Office issued an Advisory Action where the Patent Office acknowledged that the terminal disclaimer did overcome the obviousness-type double patenting rejections. A copy of the Advisory Action is attached as Exhibit E of the Supplemental Appendix.

Appellants further note for the record that it is unclear from the Final Office Action and Advisory Action whether claims 8, 12, 18 and 22 stand rejected. In this regard, the Final Office Action appears only to reference four rejections based on anticipation or obviousness as previously discussed where claims 8, 12, 18 and 22 do not appear in any of these rejections as identified in the Final Office Action. However, the Patent Office does seem to suggest that claims 8, 12, 18 and 22 also stand rejected at least in view of *Libin I* based on, for example, the discussion on page 7 of the Final Office Action. In view of same, Appellants kindly request clarification from the Patent Office regarding this issue. In any event, to the extent that claims 8, 12, 18 and 22 stand rejected, these claims have been appealed and are believed to be patentable over the cited art based on at least the

reasons for patentability with respect to independent claims 6 and 15 either of which claims 8, 12, 18 and 22 depend as described below in greater detail.

IV. STATUS OF THE AMENDMENTS

No Amendments After Final were filed.

V. SUMMARY OF THE INVENTION

The present invention provides an improved anti-plaque emulsion. It has been surprisingly found, that pursuant to the present invention, an emulsion having a low level of antimicrobial agent can be combined with a surfactant in an emulsifier to optimize the benefits of the antimicrobial agent. (Specification, p. 3, lines 26-29.)

The benefit to using an emulsion to carry the actives is that it enables the saliva to disperse the emulsion across the dental surfaces allowing the actives to afford a more complete oral contact with plaque-covered surfaces. The emulsion is very important as it enables water insoluble actives to become beneficial in the saliva. If the actives were not in an emulsion, the saliva alone would not extract the actives out of the oral hygiene product no matter how high the antimicrobial level. Since antimicrobials are effective in an emulsion, the level of the antimicrobial agent can be lowered which minimizes the negative sensory effects. At the same time, the antimicrobial is maintained at a level that is sufficiently low to minimize the agents' negative sensory effects. (Specification, p. 3, line 30 to p. 4, line 7.)

In this regard, it has been found that by creating an emulsion using triclosan and a surfactant, that reduced levels of triclosan can be used and an effective anti-plaque emulsion provided. This emulsion allows for improved oral contact and therefore improved antimicrobial effect is achieved. The emulsion, and its method of preparation, improve the intimate contact between the oral plaque and the plaque-fighting ingredients. Moreover, the combination allows the active ingredients to be used in lower levels so that the bad taste of the ingredients, as well as staining effect, is minimized. (Specification, p. 4, lines 8-15.)

The antimicrobial material of the present invention can be used in a variety of vehicles. In this regard, anti-plaque benefits can be provided via a chewing gum, mouthwash, oral paste, gel, or powder. Any vehicle to which the delivery system of the present invention can be added can be used. (Specification, p. 4, lines 16-19.)

Pursuant to the present invention, reduced levels of triclosan can be used. It has been surprisingly found that higher usage levels of triclosan did not show any dental benefit. However, when a pellet gum coating consisting in part of a lower triclosan level mixed in an emulsion with a surfactant (also at a reduced level), emulsifier and flavor benefits were surprisingly evident. (Specification, p. 4, lines 20-24.)

The level of triclosan in an emulsion should be approximately 3% to about 30% weight percent of the emulsion, preferably approximately 7% to 20% and most preferably approximately 15%. The level of the surfactant should be approximately 0.1% to about 10% weight percent of the emulsion, preferably approximately 1.0% to about 7%, and most preferably approximately 2%. Water is typically used in an emulsion. When CPC is used, the water is found in the aqueous CPC solution. Optionally, emulsions can also contain sweeteners. (Specification, p. 4, lines 25-31.)

The preferred embodiment of the invention is the use of the emulsion in a chewing gum, preferably a sugarless chewing gum (because the invention promotes dental health a non-cariogenic sweetener is preferred) and most preferably the emulsion would be included in the pellet coating of a sugarless gum. As mentioned above, the emulsion can also be incorporated into other oral hygiene products. (Specification, p. 5, lines 1-5.)

Chewing gum generally consists of a water insoluble gum base, a water soluble portion and flavors. The chewing gum of the present invention can be made of a variety of different and suitable ingredients. (Specification, pp. 5-9.)

An example of a chewing gum composition according to an embodiment of the present invention was prepared as follows:

EXAMPLE 1
PELLET GUM CENTER

<u>INGREDIENT</u>	<u>PERCENT</u>
Sorbitol & Liquid Sorbitol	47.00%
Base	32.00%
Calcium Carbonate	15.00%
Flavor	4.38%
Glycerin	0.75%
Encapsulated High Intensity Sweeteners	0.87%

The ingredients were mixed conventionally and formed into 1 gram pillow-shaped pellets. The following coating was then applied to the pellets at a level to yield a final piece size of 1.52 grams. (Specification, p. 9, lines 11-23.)

EXAMPLE 2
PELLET GUM COATING (dry composition)

<u>INGREDIENT</u>	<u>PERCENT</u>
Palatinit Course	57.83%
Palatinit Fine Powder	30.40%
Gum Talha	6.20%
Color	1.44%
Encapsulated High Intensity Sweeteners	0.53%
Flavor	2.02%
Triclosan	0.50%
CPC solution (25%)	0.40%
Hydroxylated Lecithin	0.40%
Talc Powder	0.16%
Carnauba Wax	0.12%

The pellet gum coating pursuant to an embodiment of the present invention was prepared as follows: Coarse Palatinit and Gum Galha were dissolved in water. Palatinit fine powder, color, and encapsulated high intensity sweetness were then dispersed into the solution to make a syrup suspension (73% solids), which was used to pan coat the gum centers by a conventional method. (Specification, p. 10, lines 1-19.)

The Emulsion was made in a multi-step process. First, the flavor components were blended and warmed until all were dissolved. Second, triclosan was dissolved into flavor. Third, hydroxylated lecithin was mixed into flavor/triclosan. Separately, the CPC and water were mixed very slowly—agitation was avoided as it will cause foaming and prolong the dissolution of the CPC. When CPC was dissolved in the water, it was combined with other ingredients and agitated well during this combination. When the emulsion was milky white, it was added to the shell coating on the gum pellets by conventional pan coating methods after syrup application was completed. (Specification, p. 10, lines 20-30.)

The remaining pellet coating ingredients, talc and carnauba wax, were applied separately after the pellets had dried to act a polishing ingredient. Appellants conducted an experiment that compared the coated gum made pursuant to an embodiment of the present invention with a placebo control. The results indicated that the gum made pursuant to an embodiment of the present invention was effective at reducing plaque despite lower levels and lower total dose of active ingredients. Furthermore, the gum was pleasant to chew thereby increasing the likelihood of regular use. (Specification, pp. 11-13.)

VI. ISSUES

The issues on Appeal are as follows:

1. Would the anti-plaque emulsion and the method for reducing plaque as defined by Claims 1, 2, 4, 5, 15, 19 and 23 have been novel under 35 U.S.C. §102 in view of *Libin I*?

2. Would the anti-plaque emulsion and the method for reducing plaque as defined by Claims 3, 4, 20, 21 and 24 have been obvious at the time of the invention to one of ordinary skill in the art under 35 U.S.C. §103 over *Libin I*?

3. Would the anti-plaque emulsion, the anti-plaque chewing gum and the method for reducing plaque as defined by Claims 1-7, 9-11, 13, 15-17 and 19-21 have been novel over *Andersen*?

4. Would the anti-plaque emulsion, anti-plaque chewing gum and the method for reducing plaque as defined by Claims 1, 2, 5-7, 9, 13-16 and 19 have been obvious over *Hill* and *Libin I*?

VII. GROUPING OF THE CLAIMS

Appellants argue for the separate patentability of each of the independent claims separate and apart from each other set forth in detail below pursuant to the requirements of 37 C.F.R. § 1.192(7), unless otherwise specified.

VIII. ARGUMENT

A. The Claimed Invention -- Independent Claims

On appeal, Claims 1, 6 and 15 are the sole independent claims. Independent Claims 1, 6 and 15 are provided below as follows:

Independent Claim 1 recites an anti-plaque emulsion that includes an emulsifier; triclosan; and a surfactant.

Independent Claim 6 recites an anti-plaque chewing gum that includes a water-insoluble portion; and a water soluble portion that includes an emulsifier, triclosan, and surfactant.

Independent Claim 15 recites a method for reducing plaque that includes orally applying to the mouth an emulsion that includes an emulsifier, triclosan and surfactant.

B. The Rejection

Claims 1-24 have been rejected under 35 U.S.C. § 102 and/or § 103. The Patent Office essentially asserts that the cited art discloses or suggests each of the features of the claimed invention. In this regard, the Patent Office principally relies on *Libin I*, *Hill* and *Libin I* or *Andersen* in support of the anticipation and obviousness rejections.

C. Claims 1-24 are Novel and Nonobvious

Appellants respectfully submit that the rejection of Claims 1-24 under 35 U.S.C. § 102 and/or § 103 should be reversed based on the fact that the Patent Office has failed to establish a *prima facie* case of anticipation and obviousness. Appellants submit that the cited references, even if combinable, fail to disclose or suggest at least a number of features of the claimed invention. Further, Appellants believe that the only justification for combining and/or modifying the cited art is based on hindsight reasoning.

1. The Applicable Law

“Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in the prior art ...” *Akzo NV v. U.S. International Trade Commission*, 1 U.S.P.Q. 2d 1241, 1245 (Fed. Cir. 1986). The Court of Appeals for the Federal Circuit has held that “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a *single* prior art reference.” *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir. 1988) (*emphasis added*).

In this regard, “when more than one reference is required to establish unpatentability of the claimed invention, anticipation under § 102 cannot be found, and validity is determined in terms of the § 103. *Continental Can Co. USA v. Monsanto Co.*, 20 U.S.P.Q. 2d 1746, 1748 (Fed. Cir. 1991).

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

whether the claimed invention as a whole would have been obvious
to a person of ordinary skill in the art at the time the invention was

made...The foundational facts for the *prima facie* case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art...Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness...Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q.2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome “by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings.” *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). “If the examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.” *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

Further, the Federal Circuit has held that it is “impermissible to use the claimed invention as an instruction manual or ‘template’ to piece together the teachings of the prior art so that the claimed invention is rendered obvious.” *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). “One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention” *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

Moreover, the Federal Circuit has held that “obvious to try” is not the proper standard under 35 U.S.C. §103. *Ex parte Goldgaber*, 41 U.S.P.Q.2d 1172, 1177 (Fed. Cir. 1996). “An-obvious-to-try situation exists when a general disclosure may pique the scientist curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claim result would be obtained if certain directions were pursued.” *In re Eli Lilly and Co.*, 14 U.S.P.Q.2d 1741, 1743 (Fed. Cir. 1990).

2. The Rejection of Claims 1-24 under 35 U.S.C. §102 and/or §103 Should Be Reversed Because the Patent Office Has Failed to Establish a *Prima Facie* Case of Anticipation and Obviousness

Appellants respectfully submit that the Patent Office has failed to overcome its *prima facie* burden with respect to the rejection of Claims 1-24 under 35 U.S.C. §102 and/or §103. The Patent Office has improperly relied on *Libin I*, *Andersen* and/or *Hill* in support of the anticipation and/or obviousness rejections. Even if combinable, the cited art as least fails to disclose or suggest an anti-plaque emulsion that includes an emulsifier, triclosan and a surfactant, products thereof (e.g., chewing gum) and methods employing same as required by the claimed invention.

a. The Emulsion Features of the Claimed Invention

Claims 1-24 are pending on this appeal. Of these claims, claims 1, 6 and 15 are the sole independent claims. Independent claim 1 recites an anti-plaque emulsion that includes an emulsifier, triclosan and a surfactant; Independent claim 6 recites an anti-plaque chewing gum that includes, in part, a water soluble portion including an emulsifier, triclosan, and a surfactant; and claim 15 recites a method for reducing plaque that includes orally applying to the mouth an emulsion that includes an emulsifier, triclosan and a surfactant.

The present invention provides an improved anti-plaque emulsion that contains actives, such as antimicrobial agents, that can be employed to reduce plaque build-up on dental surfaces. In this regard, saliva can disperse the emulsion across the dental surfaces, thus providing the actives with a more complete oral contact of the plaque-covered surfaces. Further, the actives within the emulsion can be effective against plaque at reduced levels, thus also minimizing negative sensory effects due to the active. For example, an emulsion that includes reduced levels of triclosan has been demonstrated to be an effective anti-plaque emulsion, such as incorporated in a chewing gum product. Moreover, negative sensory effects associated with the use of triclosan, such as bad taste and staining, can be minimized. This can increase the likelihood of regular use, thus promoting the reduction of plaque build-up.

b. The Cited References Fail to Disclose or Suggest the Emulsion Features of the Claimed Invention

Appellants respectfully submit that the cited references, even if combinable, at least fail to disclose or suggest a number features of the claimed invention. The Patent Office relies on *Libin I*, *Andersen* and/or *Hill* in support of the anticipation and/or obviousness rejections. Contrary to the Patent Office position, the cited references, even if combinable, are at least deficient with respect to the emulsion features of the claimed invention.

With respect to *Libin I*, the Patent Office relies on this reference, on its own, in support of an alleged anticipation rejection of claims 1, 2, 4, 5, 15, 19 and 23 and an obviousness rejection of claims 3, 4, 20, 21 and 24. Of these claims, claims 1 and 15 are the sole independent claims. Clearly, *Libin I* fails to disclose the emulsion features as claimed.

For example, nowhere does *Libin I* disclose an emulsion or its use in relation to its anti-plaque mouth rinse. Indeed, Appellants question how the Patent Office can rely on *Libin I* where *Libin I* discloses a solubilizer that is utilized in a sufficient amount to solubilize triclosan. See, *Libin I*, Claim 1, col. 1 at lines 53-60. In this regard, *Libin I* emphasizes solubilizing, not emulsifying triclosan. This clearly contrasts the claimed invention that includes, in part, an emulsion with an emulsifier, triclosan and a surfactant. Appellants have demonstrated that the emulsion with triclosan at reduced levels can effectively reduce plaque while minimizing negative sensory effects typically associated with use of same.

Further, the Patent Office cannot be permitted to expand the meaning of the solubilizer disclosed in *Libin* to also mean an emulsifier. It is clear that *Libin I* is using Tween 20 only as a solubilizer not as an emulsifier. Moreover, the Examiner is not permitted to use extrinsic evidence to characterize Tween 20 as an emulsifier when the reference is only describing it as a solubilizer. Of course, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir. 1981) (emphasis added). Moreover, “The identical

invention must be shown in complete detail as is contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989) (emphasis added).

Yet in spite of the above, the Patent Office continues to rely on the Merck Index to support this anticipation rejection. Indeed, Appellants submit that the Patent Office’s reliance on extrinsic evidence in this case is clearly improper. It is established case law that extrinsic evidence may not be used to “expand the meaning of terms and phrases used in the reference relied upon as anticipatory of the claimed subject matter.” *In re Baxter Travenol Labs.*, 952 F.2d 388 (Fed. Cir. 1991)(emphasis added). Here, it is clear that the Patent Office is attempting to expand the meaning of Tween 20, which is described only as a solubilizer in *Libin I*, to also include an emulsifier based on extrinsic evidence, namely, the Merck Index.

Further, *Libin I* cannot be relied on solely in support of the obviousness rejection of claims 3, 4, 20, 21 and 24. As previously discussed, each of these claims depends from either of independent claims 1 and 15 and thus as a matter of law incorporates each of the features of same. Nowhere does *Libin I* disclose, let alone suggest, the emulsion features as claimed.

Again, *Libin I* fails to disclose or suggest the use of an emulsifier to form an anti-plaque emulsion, let alone an anti-plaque emulsion that includes an emulsifier, triclosan, and a surfactant as required by the claimed invention. Indeed, Appellants have found that when in emulsion form, the active ingredients, such as triclosan, are better dispersed across the dental surfaces allowing for complete oral contact with plaque covered surfaces, thus promoting the reduction of plaque on such surfaces. *Libin I* simply describes that water-insoluble triclosan requires the use of a solubilizer to form an aqueous solution. In view of same, one skilled in the art would not be inclined to modify *Libin I* to arrive at the claimed invention. Therefore, Appellants believe that *Libin I* is clearly deficient with respect to the claimed invention.

Moreover, Appellants do not believe that the Patent Office can rely solely on *Libin I* to remedy the deficiencies of *Hill* in support of the rejection of claims 1, 2, 5-7, 9, 13-16 and 19 under 35 U.S.C. § 103(a). Of these claims at issue, claims 1, 6 and 15 are the sole independent claims as previously discussed.

At the outset, Appellants question whether *Libin I* and *Hill* should be combined in the first place. Of course, obviousness can only be established by combining or modifying the teachings of

the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). The mere fact that the references can normally be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

Clearly, *Hill* provides no such motivation to combine. Indeed, the Patent Office admits that *Hill* fails to disclose the combination of an emulsifier and a surfactant as required by the claimed invention. Further, the Patent Office incorrectly relies on *Libin I* as providing a motivation or suggestion to replace the single surfactant or single emulsifier of *Hill* with the combination thereof. As previously discussed, nowhere does *Libin I* disclose emulsifiers, let alone the combination of emulsifiers and surfactants. The clear emphasis of *Libin I* relates to solubilize agents, such as triclosan, in order to enhance anti-bacterial activity. *See, Libin I*, col. 3, lines 53-60. Even if combinable, *Hill* and *Libin I* are still deficient with respect to an anti-plaque emulsion that includes an emulsifier, triclosan and a surfactant. Indeed, Appellants have demonstrated that the claimed emulsion can be effectively used to reduce plaque at reduced triclosan levels as previously discussed. Therefore, *Hill* and *Libin I*, alone or even if combinable, are deficient with respect to the claimed invention.

The Patent Office also rejects claims 1-7, 9-11, 13, 15-17 and 19-21 under 35 U.S.C. § 102(b) as allegedly anticipated by *Andersen*. The Patent Office essentially asserts that *Andersen* discloses each and every feature of the rejected claims.

Appellants respectfully submit that the Patent Office has incorrectly relied on *Andersen* as an anticipatory reference. At the outset, the Patent Office's reliance on Merck Index as extrinsic evidence allegedly demonstrating that nonionic Tween and Pluronic surfactants of *Libin I*, *Hill* and *Andersen* function as emulsifiers is clearly contrary to established law. *See*, Final Office Action, p. 15. As discussed above, the Patent Office is not permitted to expand the meaning of terms within a reference using extrinsic evidence.

Further, the clear emphasis of *Andersen*, like *Libin I*, relates to a solubilizing agent to solubilize the active agent, such as triclosan, in order to control the release of said active agent. *See, Andersen*, claim 1, col. 10 at line 57-61. Indeed, by simply admixing a solubilizer, an improved

release of active agents without an unacceptable softening of the chewing gum can purportedly be provided as further disclosed in *Andersen* at col. 4, lines 19-24. This clearly contrasts the claimed invention that requires, in part, an emulsion that includes an emulsifier, a surfactant and triclosan, with enhanced anti-plaque properties. Based on at least these reasons, *Andersen* is deficient with respect to the claimed invention.

What the Patent Office has done is to apply hindsight reasoning to modify and/or combine the cited art to arrive at the claimed invention. Of course, this is improper. “To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.” *W.L. Gore & Associates, Inc. v. Garlock, Inc.* 220 USPQ 303, 312-313 (Fed. Cir. 1983). Again, *Libin I* and *Andersen* primarily relate to solubilizers and purported effects thereof. *Hill* primarily relates to the use of a single emulsifier or single surfactant. This clearly contrasts an anti-plaque emulsion that includes an emulsifier, a surfactant and triclosan, products thereof (e.g., chewing gum) and methods for reducing plaque employing same as required by the claimed invention.

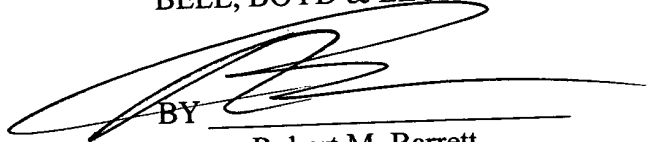
Accordingly, Appellants respectfully request that the rejection of Claims 1-24 under 35 U.S.C. § 102 and/or § 103 be reversed.

IX. CONCLUSION

Appellants' claimed invention set forth in claims 1-24 is neither taught nor suggested by the cited references, either alone or in combination. The Patent Office has failed to establish a *prima facie* case of anticipation and/or obviousness with respect to the rejection of the claimed invention. Accordingly, Appellants respectfully submit that the rejection of pending claims 1-24 as anticipated and/or as being obvious is erroneous in law and in fact and should therefore be reversed by this Board.

Respectfully submitted,

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BY _____

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APPENDIX

WE CLAIM:

1. An anti-plaque emulsion comprising:
an emulsifier;
triclosan; and
a surfactant.
2. The anti-plaque emulsion of Claim 1 wherein the surfactant is cetylpyridinium chloride.
3. The anti-plaque emulsion of Claim 1 wherein triclosan comprises approximately 3% to about 30% weight percent of the emulsion.
4. The anti-plaque emulsion of Claim 1 wherein the surfactant comprises approximately 0.1% to about 10% weight percent of the emulsion.
5. The anti-plaque emulsion of Claim 1 wherein the emulsion includes water and a solvent for the triclosan.
6. An anti-plaque chewing gum comprising:
a water insoluble portion; and
a water soluble portion including an emulsifier, triclosan, and surfactant.
7. The anti-plaque chewing gum of Claim 6 including a solvent for the triclosan.
8. The anti-plaque chewing gum of Claim 7 wherein the solvent is a flavor.
9. The anti-plaque chewing gum of Claim 6 wherein the surfactant is cetylpyridinium chloride.

10. The anti-plaque chewing gum of Claim 6 wherein triclosan comprises approximately 3% to about 30% weight percent of the emulsion.

11. The anti-plaque chewing gum of Claim 6 wherein the surfactant comprises approximately 0.1% to about 10% weight percent of the emulsion.

12. The anti-plaque chewing gum of Claim 6 wherein each piece of gum includes approximately 1 mg to about 6 mg of triclosan.

13. The anti-plaque chewing gum of Claim 6 wherein the gum is in pellet form.

14. The anti-plaque chewing gum of Claim 13 wherein the emulsifier, triclosan and surfactant define, in part, a coating of the pellet.

15. A method for reducing plaque comprising the step of orally applying to the mouth an emulsion comprising an emulsifier, triclosan and surfactant.

16. The method of Claim 15 wherein the emulsion is in the form of chewing gum.

17. The method of Claim 15 wherein the chewing gum is chewed for at least five minutes.

18. The method of Claim 15 wherein the chewing gum is chewed at least three times per day.

19. The method of Claim 15 wherein the surfactant is cetylpyridinium chloride.

20. The method of Claim 15 wherein triclosan comprises approximately 3% to about 30% weight percent of the emulsion.

21. The method of Claim 15 wherein the surfactant comprises approximately 0.1% to about 10% weight percent of the emulsion.

22. The method of Claim 15 wherein each piece of gum includes approximately 1 mg to about 6 mg of triclosan.

23. The method of Claim 15 wherein the emulsion is in a mouthwash.

24. The method of Claim 15 wherein the emulsion is in a toothpaste or gel.



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ROSE, SHEP K

ART UNIT

PAPER NUMBER

1614

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Due: 4-10-03

Please find below and/or attached an Office communication concerning this application or proceeding.

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DOCKET #: 112703-211

Office Action Summary

Application No.

10 035320

Applicant(s)

BARBARA J. L. J.

Examiner

STEP 20505

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 11/04/2002
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 2, 3 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 2, 3 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d):
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1614

Applicants' November 4, 2002 responsive remarks are not accompanied by any terminal disclaimer and state further that a suitable terminal disclaimer will only be filed upon the notice of allowable subject matter.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The USPTO practice is not to withdraw any obviousness-type double patenting ground of rejection until suitable terminal disclaimers are in fact filed and accepted by the USPTO.

Claims 1-22 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-32 of allowed, now patented, copending Application No. 09/453,383 now US Patent No. 6436369 issued August 20, 2002. Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is an obviousness-type double patenting rejection because the conflicting claims have in fact been patented.

Art Unit: 1614

This application is a continuation of allowed (now patented) Application Serial No. 09/453,383, filed December 2, 1999, now U.S. Patent 6436369 with allowed claims 28 to 32 to an antiplaque chewing gum in pellet form comprising a water insoluble portion, a water soluble portion, and a coating on the pellet which comprises an emulsifier, triclosan and a surfactant, with about 1mg to about 6 mg of triclosan included in each piece of gum, and a method for reducing plaque by the step of orally applying said chewing gum to the mouth, raising an issue of obviousness-type double patenting of claim 6 to 14, 16 to 22 herein, to the same chewing gum, (claim 17 and 18 imply a chewing gum should be recited in claim 15), also, of claims 1 to 5 and 15 generic thereto.

The claims require, in addition to triclosan, both an emulsifier and a surfactant, but do not require that these be in a coating on the chewing gum. The surfactant is cetylpyridinium chloride in claims 2, 9 and 19. the term of these claims "emulsifier" encompasses species other than set forth in the specification on page 6, lines 27-28. "Emulsifiers may include lecithin, glyceryl monostearate, or other mono and diglycerides. . . " (There are also softeners), and a typical chewing gum has both (as see page 7, lines 1 to 14).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 to 22 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10 of U.S. Patent No. 6,355,265 in view of Libin (I) U.S. 5,236,699 (details as noted below). It

Art Unit: 1614

would be obvious to employ Libin's antiplaque aqueous combination of triclosan, cetylpyridinium chloride surfactant and two emulsifiers tween 20 and pluronic L64, inherently forming an emulsion in water as the medicament in the coating on the patented chewing gum, Merck Index establishing in the record that these two surfactants are emulsifying agents.

Claims 1 to 22 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10, 12, 29 of U.S. Patent No. 6,350,980 in view of Libin (I).

Claims 1 to 22 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 19, 28 of U.S. Patent No. 6,322,806 in view of Libin (I).

Claims 1 to 22 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, 12, 17, 26 of U.S. Patent No. 6,290,985 in view of Libin (I).

From the teaching of the Libin reference taken with these commonly assigned patented claims (to a medicament in the coating on chewing gum), it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed triclosan antiplaque invention. Therefore the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the Libin reference, especially in the absence of evidence to the contrary.

Art Unit: 1614

Commonly assigned (Wrigley) patents with claims to medicament (broadly) in coatings on chewing gum, namely: U.S. 6,355,265 (claims 1 and 10); U.S. 6,350,480 (claims 10, 12 and 29); U.S. 6,322,806 (claims 1, 10, 19, 28); U.S. 6,290,985 (claims 1, 9, 12, 17, 26) raise an issue of obviousness-type double patenting.

Applicants July 22, 2002 response, after noting that claims 1 to 22 have been rejected on allowed claims 28 to 32 of parent application Serial no. 09/453,383 (now U.S. Patent 6436369) on the ground of non-statutory double patenting, states that a terminal disclaimer" will be filed upon issuance of copending application 09/453,383, which in fact issued August 20, 2002 but the USPTO policy practice and procedure is to reject copending applications for obviousness-type double patenting, and not to wait until they issue as patents.

Applicants July 22, 2002 response notes that claims 1, 2, 4, 5, 15, 19 and 23 have been rejected by Libin (I) U.S. 5,236,699 as anticipated, 35 USC 102 (B), the USPTO Examiner following the MPEP to establish by extrinsic evidence, that Libin describes antiplaque triclosan with cetylpyridinium chloride surfactant as well as with two (2) emulsifying agents: Tweens 20 and Pluronic L64 surfactants, see Merck Index entries for both. The MPEP Sections have been cited to applicant.

Applicants' counsel's responsive remarks, seemingly questions relevance on the MPEP sections permitting the USPTO Examiner to rely on Merck Index to establish the fact that Libin who has two emulsifiers Tween 20 and Pluronic L64 with the same triclosan and the same cetyl pyridinuim chloride surfactant as his antiplaque composition, can be an anticipation, 35 U.S.C. 102.

Art Unit: 1614

Claims 1 to 5, 15, 19, 20, 21, 23 and 24 which do not recite or require any chewing gum, are drawn to antiplaque compositions and oral methods for reducing plaque, wherein the composition comprises (A) triclosan as the antiplaque agent, (B) an emulsifier, and (C) a surfactant, which, in dependent claims 2 and 19 is cetylpyridinium chloride, in dependent claims 3 and 20 there is 3% to 30% triclosan, in dependent claims 4 and 21, there is 0.1 to 10% surfactant, in dependent claim 5 there is (D) water and (E) a solvent for the tri-closan.

Here, the Examiner can properly rely on extrinsic evidence (Merck Index) to establish with certainty that that Libin (I) U.S. 5,236,699A, 17 August 1993, a reference introduced into the record by applicants on their PTO-1449 IDS, is an anticipation, under 35 U.S.C. § 102, of claims 1, 2, 4, 5, 15, 19 and 23 because 2 (two) of the surfactants employed with Libin's enhanced anti-plaque combination of (a) Triclosan and (b) cetylpyridinium chloride, are described by Merck Index as emulsifiers, (c) Tween 20 surfactant, and (d) Pluronic L64 surfactant.

Claims 1, 2, 4, 5, 15, 19 and 23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Libin (I) U.S. 5,236,699A, 17 August 1993, who describes an enhanced activity anti-plaque aqueous alcoholic vehicle for mouthwash, comprised of: (a) Triclosan, a water insoluble anti-plaque agent, 0.01 to 0.05%; (b) cetylpyridinium chloride surfactant a water soluble antiplaque agent (it's a cationic surfactant as well), 0.020% to 0.030%; (c) Tween 20, a triclosan solubilizer, 0.5 to 2%, a polysorbate pharmaceutical emulsifier and surfactant dispersing agent, (according to Merck Index entry 7742); (d) Pluronic L64, 10%, as a foaming agent, which is an emulsifier,

Art Unit: 1614

(according to Merck Index, entry 7722), said combined agent coaction of (a) and (b) to afford highly effective enhanced antibacterial activity against dental plaque, (e) water, 67%; and (f) alcohol, 18%.

Libin fully anticipates claims 1, 2, 4, 5, 15, 19 and 23 (mouthwash) under 35 U.S.C. § 102, since these claims either recite no percentage concentration levels for any of the components, and the surfactant percentages of claim 4 are described, as noted above.

Claims 3, 4, 20, 21 and 24 are rejected as obvious, under 35 U.S.C. 103 over Libin: they differ from Libin (I), in requiring 3% (a) Triclosan instead of 0.05%, and while the chewing gum claims 6-14 and 16-18 are not described, there is clearly only an obvious difference from a mouthwash in Libin in the toothpaste or gel of claim 24.

Claims 6 to 13, 15 to 18 and 22 recite a chewing gum wherein triclosan, an emulsifier and a surfactant are "in a water soluble portion", which only in claim 14, in part, can be a coating of the pellet of the pellet chewing gum recited only in claim 13, and, and only in claim 22 does each piece of gum include 1mg to 6 mg of triclosan. In none of these triclosan chewing gum claims is it recited and required that all of the triclosan, surfactant and emulsifier be a coating on the chewing gum, or that it be a coating on pellet chewing gum, or that there be 1 mg. To 6 mg. of triclosan in a coating on chewing gum, or on pellet chewing gum. Only in claim 13 is the chewing gum in pellet form, and only in claim 14 is the triclosan, in part, in a coating of the pellet with an emulsifier and surfactant.

Art Unit: 1614

The term "a water soluble portion" recited in claim 6, in which the triclosan, an emulsifier and surfactant are "included", (although perhaps meant to imply a water soluble coating on the chewing gum) reads on the chewing gum base vehicle, per se, since Hill, U.S. 5380530, at page 8, lines 63 to 68 states the fact that slab chewing gum base is more than 75% water soluble materials, such as sugars, sugar substitutes corn syrup and the like.

Claims 7 to 12 depend on claim 6, and read on triclosan in the chewing gum base of a slab or stick or sheet of chewing gum, which customarily have emulsifiers and surfactants.

Claims 1, 2, 5-7, 9, 13-16 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hill U.S. 5,380,530A, 10 January 1995, taken with Libin (I) (details as noted above), it being within the level of skill of the art to replace a single surfactant-emulsifier with a combination of two of them, as described by Libin (I), (details as noted above).

Hill describes an anti-plaque emulsion coating on chewing gum (same as herein) comprising (a) an emulsifying agent (column 10, lines 51-55); (b) Triclosan (same as herein) (column 9, line 58, column 15, line 26, in Example 17, Table II, 0.2 to 1.0%, and claim 2; and (c) cetyl pyridinium chloride (same as herein) (column 15, line 30 and claim 2; and (d) a surfactant, claim 9, column 10, lines 11-50; (TABLE I, "PLURONICS", etc.) and (e) chewing gum plasticizer softening agents which happen to be applicants' "emulsifiers" according to the recitals of this specification at page 6, lines 22-28 and

Art Unit: 1614

Example 2 page 10: Hydroxylated lecithin in the Example, lecithin, glycerol monostearate, or other mono or diglycerides, Hill describing applicants' emulsifiers acetylated monoglycerol triacetate, glycerol diacetate, and lecithin, 0.4 to 0.6% at column 19, line 65 to column 20, line 11.

Hill (details as noted above) emulsion coats triclosan on chewing gum (same as herein) and renders obvious (35 U.S.C. § 103) claims 1, 2, 5-7, 9, 13-16, and 19 the rejection being made under 35 U.S.C. § 103, but differs from, and does not explicitly anticipate or describe claims 3, 10, 20 and 22 in the percentage of Triclosan (1% versus 3%), and differs from claims 4, 11 and 21 in not specifying the percentage of surfactant in the anti-plaque Triclosan chewing gum coating, however, clearly, it being within the level of skill of the art to replace equivalent percentages of a single surfactant-emulsifier with percentages of a combination of two of them, as described by Libin (I), (details as noted above), the Examiner relying on Merck Index extrinsic evidence to establish that claim encompassed surfactants of Hill are known as emulsifiers as well.

Hill, according to applicants' counsel's remarks does not anticipate these claims under 35 U.S.C. § 102 because it is argued, herein a single surfactant and emulsifier are employed with Triclosan to emulsion coat the chewing gum, but to interchange equivalent percentages of a combination of a surfactant and an emulsifier to attain the same goal is clearly prima facie obvious 35 U.S.C. § 103.

Hill emulsion coats triclosan and cetylpyridinium chloride (same as herein) onto "slabs" sheets of chewing gum base, (in contrast to onto candy coated gum nuggets

Art Unit: 1614

(col. 9, lines 1 to 15) or placing his claimed emulsions into liquid center chewing gums or into chewing gum base mixes as in Wrigley chewing gums (col. 8, lines 38-68) which are more than 75% water soluble materials such as sugars, sugar substitutes, corn syrup, etc.) Claim 6 herein recites such water-soluble portions, at the chewing gum base, to include the triclosan.

Hill explicitly applies his emulsion coatings of triclosan, and/or cetylpyridinium chloride (same as herein) onto chewing gum in sheet or slab form (column 21, lines 10 to 22, column 22, line 19 to 22, 28, 29, 47, 48 onto a sheet of gum, emulsion coating on the chewing gum sheet, sheet of chewing gum, column 23 lines 1, 2 chewing gum sheet.

The term "chewing gum" in applicants' claims 6 to 12, 16 to 18 and 22 encompasses Hill's preferred enabled examples of slab or sheet "slabs" of chewing gum.

Only in applicants' dependent claims 13 and 14 is the chewing gum defined as in pellet form, and only in dependent claim 14 is the triclosan emulsion chewing gum coating (Same as Hill's), and only in part, a coating of the pellet.

"Pellet" chewing gum may be the non-preferred "costly alternative" to Hill's desired slab forms of chewing gum, set forth by Hill at column 9, lines 1 to 16, in contrast to chewing gum wherein medicament is in a candy coating on a gum nugget or center, commonly called "candy coated gum", but these are clearly contemplated by Hill as encompassed by the triclosan and cetylpyridinium emulsion coating of "chewing gum"

Art Unit: 1614

in claim 2 of Hill, as see column 23, lines 6 to 10, in any desired mg quantity, on a wide range of piece size and shape, "mints", sticks, slabs, lines 45 to 52 modifications are with the scope of the claims.

Claims 1-7, 9-11, 13, 15-17 and 19-21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Anderson et al., U.S. 5,487,902A, 30 January 1996, who describe (column 11 line 58 to column 12 line 5) any chewing gum (candy coated "bits" or sticks) with active agents to be chewed for 2 to 30 minutes, said chewing gums including: (a) Triclosan (column 9, line 24; 0.1 to 10% at column 10, line 26 and 0.01 to 30% at column 12, line 53; (b) cetylpyridinium chloride at column 8, lines 54-55; and solubilized with emulsifying solubilizing surfactants "AT LEAST ONE" and "A COMBINATION OF SEVERAL" at column 6, lines 21-22 and claim 12; (c) solubilizers-surfactants (all known and approved for use as emulsifiers) (column 5, line 57 to column 6, line 24, 1% to 10% at column 10, lines 56-57, column 12, line 55 and claim 4; (d) emulsifying active agent solubilizing agents, column 7, lines 8-26, 0 to 12%.

Anderson et al. anticipate claims 1-7, 9-11, 13, 15-17, and 19-21 but does not explicitly specify a weight of 1 mg to 6 mg of Triclosan per piece of gum as in claims 12 and 22, and do not explicitly state to chew the gum three times per day as in claim 18, and beyond chewing gum, do not further describe a mouthwash toothpaste or gel as in claims 23 and 24.

Applicants' counsel's remarks have been considered but are seen to have inadvertently overlooked the terms "AT LEAST ONE" and A COMBINATION OF SEVERAL" (c) solubilizer surfactants known as emulsifiers as well as the (d) emulsifiers

Art Unit: 1614

employed by Anderson in chewing gum base with (a) Triclosan and (b) cetylpyridinium chloride, which in the claims herein are neither recited to be in a coating on the gum, or inside the chewing gum base center itself, while applicants' only claimed coating, in claim 14 "IN PART" unfortunately does not recite or require that 100% of the Triclosan is in the pellet coating on the pellet center, there being "NO TRICLOSAN WHATSOEVER" in applicants' described and enabled chewing gum base or gum pellet center as a careful review of the specification will establish to anyone's satisfaction.

The remarks and arguments by applicants' attorney (who has not been qualified as an expert) are not considered to be the opinion of an expert, see In re Schulze 145 USPQ 716"... Argument of counsel cannot take the place of objective evidence ...". They certainly reveal a lack of recognition that claims encompassed surfactants function as emulsifiers. There is no Rule 132 Declaration of any expert by applicants who are considered to be skilled in the art to buttress or to support the argument, which is unsubstantiated. Counsel's remarks have been considered, but are not seen as a substitute for a Rule 132 Declaration of an expert, when technical counsel is arguing facts. Attorney argument is not evidence, unless it is an admission. See: In re De Blauwe, 222 USPQ 191, 196; Meitzner v. Mindick, 193 USPQ 17, 22, In re Pearson, 181 USPQ 641, 646, In re Lindner, 173 USPQ 356, 358; In re Schalze, 145 USPQ 716, 718; In re Cole, 140 USPQ 230, 233, and In re Walters, 77 USPQ 609, 610. The following arguments have been made in the remarks:

"LIBIN" does not describe the use of an emulsifier ..., "... to overcome the emulsifier element deficiency in Libin ..." In this regard, Libin does not disclose an

Art Unit: 1614

emulsifier...” “... Neither Hill nor Anderson discloses the use of a nonionic surfactant as an emulsifier ...”; “... Clearly the Hill and Anderson references do not teach the use of a nonionic surfactant as an emulsifier ...”, “indeed Hill discloses a variety of surfactants but not that such surfactants may also function as an emulsifier”. “Thus combining the teaching of Libin with that of Hill would fail to arrive at applicants’ claimed invention because the required emulsifier element would be missing”.

Applicant’s arguments have been fully considered, but are clearly erroneous. Libin’s Tweens 20 and Pluronics 264 are not only described by Merck Index as emulsifying agents, they are also described by Anderson et al as apt solubilizing surfactants for active agents in chewing gum known to be emulsifiers. Anderson et al describe both of Libin’s surfactant Tweens and Pluronics in Examples as solubilizing surfactants known for use as emulsifiers. Both Hill and Anderson do in fact teach the use of non-ionic surfactants as emulsifiers. See: In Hill, column 10 line 11, suitable surfactants and emulsifiers for use in the present emulsion coating for gum include: (“Tweens”) at lines 49 and 50, line 23 to 25 (polyoxyethylene derivatives of sorbitan esters) (“Pluronics” mentioned at lines 45 to 49), Table I, columns 11 and 12, (both in claim 9 of Hill). Anderson et al teach both of Libin’s Pluronic and Tween surfactants to be known for use as emulsifiers (See column 6, lines 1 to 24 as well as Tweens in Examples 48 to 75, and 100 to 103, 113, 146 Pluronics in Examples 76 to 87, and note both in Anderson et al’s claims 4 and 5.

Art Unit: 1614

Applicants' attorney's arguments do not reflect USPTO practice. The remarks include: As previously argued, Libin I fails to disclose the emulsion features of independent Claims 1 and 15. Nowhere does Libin I disclose an emulsion or its use in relation to its anti-plaque mouth rinse. Applicants question how the Patent Office can rely on Libin I where Libin I discloses a solubilizer that is utilized in a sufficient amount to solubilize triclosan. See, Libin I, Claim 1, col. 1 at lines 53-60. In this regard, Libin I emphasizes solubilizing, not emulsifying triclosan. Moreover, as discussed above the Patent Office is not permitted to expand the meaning of the solubilizer disclosed in Libin I to also mean an emulsifier. It is clear that Libin I is using Tween 20 only as a solubilizer not as an emulsifier. While it is perhaps arguable that Tween 20 is also useful as an emulsifier, the reference clearly does not disclose using it as one. Moreover, the Examiner is not permitted to use extrinsic evidence to characterize Tween 20 as an emulsifier when the reference is only describing it as a solubilizer. As noted above, extrinsic evidence is not allowable to "expand the meaning of terms in a reference".

Applicants' attorney's remarks on Anderson et al in advertently overlook the above noted teaching of Anderson et al to employ solubilizing surfactants known to be useful emulsifiers. It is argued:

In the Office Action, claims 1-7, 9-11, 13, 15-17 and 19-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Andersen. The Patent Office essentially asserts that Andersen discloses each and every feature of the rejected claims.

Applicants submit that the Patent Office again incorrectly relies on Andersen as an anticipatory reference. The Examiner's position that " they do not have to state that their surfactants are emulsifiers, if extrinsic evidence (Merck Index) establishes that such encompassed species of nonionic surfactants to be used are emulsifiers." Is clearly contrary to established law. See, Office Action, p. 89. It is argued:

Andersen, like Libin I, requires a solubilizing agent to solubilize the active agent, such as triclosan, in order to control the release of said active agent. See, Andersen, Claim 1, col. 10 at line 57-61. Further, Andersen clearly makes a distinction between the uses of an emulsifier as compared to solubilizers. Again, while it might be arguable that these solubilizers may also be emulsifiers, it is clearly not described as so in the Anderson reference. (This argument is contrary to Anderson to use solubilizer known as emulsifiers). Moreover, extrinsic evidence is "not permitted" to expand the meaning of terms in a reference.

The Examiner properly relies on Merck Index as extrinsic evidence showing that those of ordinary skill in that art know that the nonionic Tween and Pluronic surfactants of Libin, Hill and Anderson function as emulsifiers. See MPEP § 2131.01 (d) and MPEP § 2112-2113 for case law on inherency. See: Atlas Powder versus Ireco, 51 USPQ 2d 1943.

The legal basis for an inherency rejection, one that can properly be made under 35 U.S.C. § 102/103, is set forth in MPEP § 2112-2112.02 citing In re Fitzgerald et al., 205 USPQ 594. When the reference discloses all the limitations of a claim except a

Art Unit: 1614

property or function, whether or not the reference inherently possesses properties or renders obvious the claimed invention, there is basis for shifting the burden of proof to applicant. Also, MPEP § 2183-2184, when the reference teaches all the claim limitations except a claimed element, an examiner is not certain whether the element disclosed in the reference is an equivalent to the claimed element and therefore anticipated, or whether the prior art element is an obvious variant of the claimed element.

Here, the Examiner can rely on extrinsic evidence (Merck Index) to establish with certainty that that Libin (I) U.S. 5,236,699A, 17 August 1993, a reference introduced into the record by applicants on their PTO-1449 IDS, is anticipation, under 35 U.S.C. § 102, of claims 1, 2, 4, 5, 15, 19 and 23 because 2 (two) of the surfactants employed with Libin's enhanced anti-plaque combination of (a) Triclosan and (b) cetylpyridinium chloride, are described by Merck Index as emulsifiers, (c) Tween 20 surfactant, and (d) Pluronic L64 surfactant. These claims are clearly anticipated by Libin (I) U.S. 5,236,699A, 17 August 1993, who describes an enhanced activity anti-plaque aqueous alcoholic vehicle for mouthwash, comprised of: (a) Triclosan, a water insoluble anti-plaque agent, 0.01 to 0.05%; (b) cetylpyridinium chloride, a water soluble antiplaque agent (it's a cationic surfactant as well), 0.020% to 0.030%; (c) Tween 20, a triclosan solubilizer, 0.5 to 2%, a polysorbate pharmaceutical emulsifier and surfactant dispersing agent, (according to Merck Index entry 7742); (d) Pluronic L64, 10%, as a foaming agent, which is an emulsifier, (according to Merck Index, entry 7722), said

Art Unit: 1614

combined agent coaction of (a) and (b) to afford highly effective enhanced antibacterial activity against dental plaque, (e) water, 67%; and (f) alcohol, 18%.

Libin fully anticipated claims 1, 2, 4, 5, 15, 19 and 23 (mouthwash) under 35 U.S.C. § 102, since these claims either recite no percentage concentration levels for any of the components, and the surfactant percentages of claim 4 are described, as noted above.

In an attempt to advance the prosecution of this application to a more timely issue, the Examiner can properly substantiate in the record the well known fact, as a matter of common knowledge in the art, that the two (2) surfactants of LIBIN (I) function as emulsifiers according to Merck Index. The claims that had been rejected under 35 U.S.C. § N 102/103 on Libin alone on a theory of inherency, based on this well known substantiated fact MPEP § 706.02 (a), 707.07 (f) can properly be rejected either on 35 U.S.C. § 102 or on 35 U.S.C. § 103.

While applicants herein have 100% of the Triclosan and cetylpyridinium chloride in the pellet outer coatings, and 0% of each inside their chewing gum base center, claims 6, 13 and 14 are clearly not commensurate in scope with applicants' disclosed enabled and described invention, but the broadest reasonable interpretation of these claims metes and bounds must be given.

Claim 1 does not recite or even require that --said anti-plaque emulsion comprise a coating of the pellet chewing gum in pellet form--.

Art Unit: 1614

Claim 1 does not define the emulsion as defined in the specification on page 6, lines 22-28 and Example 2 on page 5 as said emulsifier being selected from the Markush group consisting of --hydroxylated lecithin, lecithin, glycerol monostearate, other mono-and diglycerides--. The term "surfactant" in claim 1 clearly encompasses known species of surfactants which function inherently and have been described in the prior art as emulsifiers, by Anderson et al, (as noted above), and by Hill (as noted above).

The Courts have held that there is no requirement that those of ordinary skill in the art know of the inherent property. See MPEP 2131.01(d) and MPEP § 2112-§2113 for case law on inherency. Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124.<

Atlas Powder Co. C. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999)

"Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art ... however, the discovery of a previously unappreciated property of a prior art composition patentably new to the discover. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Mehl/Biophile International Corp. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999)

Thus viewed as a whole, the Polla disclosure shows that the "natural result flowing from the operation as taught would result in alignment of the laser light over the hair follicle,

as claimed.” This was true even though Polla did not mention the goal of hair removal. Therefore, the Court held that the ‘192 patent was invalid as anticipated.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

INHERENCY OF METHODS. Ex parte Novitski 26 USPQ 1389 (BPAI 1993)

Meh/Biophile International Corp. V. Milgraum. 52 USPQ2d 1303 (Fed. Cir. 1999)

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1614

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday and Thursday from 7:30 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



**SHEP K. ROSE
PRIMARY EXAMINER**

Rose/LR
January 9, 2003

Notice of References Cited

Application No.

09/044970

Applicant(s)

BARABOLAK, J.

Examiner

5/00/00

Group Art Unit

1614

Page ____ of ____

U.S. PATENT DOCUMENTS

* A	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	6436369 B2	8/20/02	BARABOLAK, J. (09/453383)	424	48
B					
C					
D					
E					
F					
G					
H					
I					
J					
K					
L					
M					

FOREIGN PATENT DOCUMENTS

* N	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
N						
O						
P						
Q						
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S						
T						

NON-PATENT DOCUMENTS

* U	DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
U		
V		
W		
X		

* A copy of this reference is not being furnished with this Office action.
(See Manual of Patent Examining Procedure, Section 707.05(a).)



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,320	11/08/2001	Roman M. Barabolak	112703-211	2531

29156 7590 05/16/2003

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135



EXAMINER

ROSE, SHEP K

ART UNIT PAPER NUMBER

1614

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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ATTY: *PMB*

DOCKET #: *112703-211*



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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED:

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☐ THE PERIOD FOR RESPONSE:

- a) ☐ is extended to run _____ or continues to run _____ from the date of the final rejection
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☒ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed APRIL 22 2013 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:
- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
 - b. ☐ They raise new issues that would require further consideration and/or search. (See Note).
 - c. ☐ They raise the issue of new matter. (See Note).
 - d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
 - e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.
3. ☐ Upon the filing an appeal, the proposed amendment ☐ will be entered ☐ will not be entered and the status of the claims will be as follows:

Claims allowed: _____
Claims objected to: _____
Claims rejected: _____

However;

☒ Applicant's response has overcome the following rejection(s): the accepted Terminal Disclosures overcome the obvious double patenting grounds set out on pages 1 to 5 of the Final Rejection Office Action.

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because the claims remain rejected on the art as set out on pages 6 to 19 of the Final Office Action. All of these arguments have already been considered and found unpersuasive. There is no novelty in these claims.
5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

- ☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.
- ☐ Other

Sherp Rose
SHEP K. ROSE
PRIMARY EXAMINER